UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

DATE: January 17, 2013

SUBJECT: **Cyantraniliprole.** Dissipation of Dislodgeable Foliar Residues from Peppers Treated with SYN545377 WG (40).

PC Code: 090098 **DP Barcode:** D407968

Decision No.: 451670 **Registration No.:** 100-RUEU, 352-IAL

Petition No.: 1F7894 **Regulatory Action:** Section 3

Risk Assessment Type: NA **Case No.:** NA

TXR No.: NA **CAS No.:** 736994-63-1

MRID No.: 48432542 **40 CFR:** to be determined (new active ingredient)

FROM: Nancy Tsaur, Chemist
Risk Assessment Branch 3 (RAB3)
Health Effects Division (7509P)

THROUGH: Barry O'Keefe, Senior Biologist, ORE Team Leader
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TO: Nancy Tsaur, Chemist
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EPA Reviewer: Nancy Tsaur   **Signature**: _____

Risk Assessment Branch 3 (RAB3), Health Effects Division (7509P)   **Date:** January 17, 2013

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DATA EVALUATION RECORD

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STUDY TYPE: Determination of Dislodgeable Foliar Cyantraniliprole Residues from Pepper Foliage Treated with SYN545377 WG (40): OPPTS 875.2100

PC CODE: 090098

TEST MATERIAL   SYN545377 WG (40) is formulated as a water-dispersible granule containing a nominal 40% active ingredient, cyantraniliprole.

SYNONYMS: Cyantraniliprole; 3-bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide
CAS No. 736994-63-1.

CITATION: Authors: Emily Shepard
                        Title: Cyantraniliprole – Dissipation of Dislodgeable Foliar Residues on Peppers treated with a Water-Dispersible Granule (WG) Formulation of Cyantraniliprole
                        Amended Report Date: April 26, 2011
                        Analytical Laboratory: ABC Laboratories, Inc.
                                              7200 E. ABC Lane
                                              Columbia, MO 65202
                        Identifying Codes: Report Number 65751; Task Number TK0025707; MRID 48432542; Unpublished

SPONSOR: Syngenta Crop Protection, LLC
                        410 Swing Road
                        P O Box 18300
                        Greensboro, NC 27419-8300
                        U.S.A.

EXECUTIVE SUMMARY:

This study was designed to determine the dissipation of dislodgeable foliar residues (DFR) of cyantraniliprole applied to pepper plants. During the 2010 growing season, three test sites were examined, Germansville, Lehigh County, PA; Chula, Tift County, GA; and Fresno, Fresno County, CA. Three applications of SYN545377 WG, a water-dispersible granular formulation containing 40.7% active ingredient, cyantraniliprole, was made 5 ± 1 days apart to pepper foliage at the target rate of 0.134 lb ai/A per application. Foliar broadcast spray applications were made using a CO_2 backpack boom sprayer and a spray volume of 2 to 50 gallons of spray solution per acre (GPA). A surfactant was not added to the spray mixture.

DFR samples consisting of 40 leaf punch discs measuring approximately 1 inch in diameter were collected at specified intervals. At each site samples were targeted for collection prior to each application, at 0 hours after each application (when dry), at 6 hours after the third application, and at 1, 2, 4, 7, 10, 14, and 21 days after the third application, with the addition of 28- and 35-day sampling intervals

at the CA site. At the GA site, the 6 hours after application samples could not be collected due to rainfall. The samples were collected when leaves had dried (7.5 hours after application). The one day samples at this site were not collected due to oversight of the field cooperator. Three replicate leaf punch samples were collected from each treated plot (one from each subplot) at each sampling interval. One control sample was collected from the untreated plot before the first application, after each of the three applications, and at 10 days after the third application. Triplicate field-fortified samples were prepared three times during the study at each site using samples from the control plot at two fortification levels (0.025 μg/cm^2 and 0.25 μg/cm^2) to evaluate the stability of the field samples during shipping and storage.

The Registrant provided DFRs in μg/cm^2. The Registrant and HED corrected the residue data for the corresponding low level or high level average field fortification recovery for each test site. The residue data from the PA test site were corrected for overall average low and high level field fortification recoveries of 97.4% and 97.3%, respectively. The residue data from the GA test site were corrected for overall average low and high level field fortification recoveries of 92.6% and 96.5%, respectively. The residue data from the CA test site were corrected for overall average low and high level field fortification recoveries of 90.6% and 92.7%, respectively.

At each of the test sites, the highest DFR value occurred immediately after the third application (0DAT3). At the PA test site the highest DFR was 0.449 μg/cm^2 or 29.9% of the application rate, and values dropped to 0.014 μg/cm^2 by 21DAT3. In GA, the highest DFR value was 0.435 μg/cm^2 or 28.1% of the application rate, and the values dropped to below the LOQ (0.005 μg/cm^2) by 14DAT3. At the CA site, the highest average DFR value was also at 0DAT3 and was 0.716 μg/cm^2 or 47.3% of the application rate, and values dropped to 0.046 μg/cm^2 by 35DAT3.

Half-life estimates of cyantraniliprole dissipation as calculated by the Registrant and HED were essentially the same. HED's use of individual DFR values in regression calculation most likely explains the minor differences. The Registrant modeled best fit DFR decline curves using the natural log-transformation (ln) of the residues to generate a log-linear graph to estimate dissipation rate and half-life values. First-order dissipation kinetics were assumed to generate dissipation curves for cyantraniliprole. The linear regression analysis was conducted using the natural logarithm of the individual foliar residue values collected immediately after the third application through the last day of sampling.

The Registrant's calculated half-lives for cyantraniliprole on pepper leaf tissue were 3.9 days ($R^2 = 0.931$) for the PA site, 2.8 days ($R^2 = 0.812$) for the GA site and 8.4 days ($R^2 = 0.953$) for the CA site.

The calculated half-lives for cyantraniliprole on pepper leaf tissue were 3.8 days ($R^2 = 0.921$) for the PA site, 2.9 days ($R^2 = 0.842$) for the GA site, and 8.4 days ($R^2 = 0.932$) for the CA site.

The average DFR determined immediately after the third cyantraniliprole application (0DAT3) represented 29.9%, 28.1%, and 47.3% of the application rate for the PA, GA, and CA test sites, respectively.

This study met the majority of the Series 875.2100 Guidelines. The following issues of concern are noted:

- Rainfall appears to be an issue at the Georgia test site. The executive summary of the study report states that the sample which should have been collected 6 hours after the third application was not collected due to rainfall. The sample was collected 1.5 hours later at 7.5 hours after application (when the leaves were dry). It appears from the statement in the executive summary that rain fell immediately after the application potentially washing off the residues. Daily rainfall events were not documented in the study report.

- The Registrant validated the analytical method using samples fortified at levels ranging from 0.005 and 0.250 $\mu g/cm^2$. The field fortification levels were 0.025 and 0.250 $\mu g/cm^2$. These levels do not bracket the range of field sample residue levels from any of the three test sites. Individual field sample residues ranged from 0.008 to 0.766 $\mu g/cm^2$.

- Daily meteorological data were reportedly collected, but were not provided for any of the test sites for the duration of the study. Only monthly maximum and minimum temperatures and total monthly precipitation data were provided for the duration of the study. Relative humidity was provided for the day of the applications; however, wind direction/velocity, rainfall and cloud cover was not provided for any of the test sites for application day.

- The production of metabolites, breakdown products, or the presence of contaminants of concern were not discussed in the Study Report.

- Tank mix samples were not collected after application to check for uniformity.

COMPLIANCE:

Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. The study sponsor waived claims of confidentiality within the scope of FIFRA Section 10 (d)1(A), (B), or (C). The Study Report indicated that the study was conducted under EPA Good Laboratory Practice Standards (40 CFR Part 160), with the following exceptions: environmental data were not collected under GLP Standards; pesticide, fertilizer, and crop history for the test sites were not collected under GLP Standards; soil information provided by the USDA NRCS was not determined under GLP Standards; tank mixtures were not analyzed for uniformity; sample weights recorded in the field were not determined under GLP Standards (GA site); GPS coordinates were not obtained under GLP Standards; and maintenance equipment was not maintained under GLP Standards.

CONCURRENT EXPOSURE STUDY: No

GUIDELINE OR PROTOCOL FOLLOWED: Series 875, Part B: Dislodgeable Foliar Residue
                                                                    Dissipation: Agricultural, Guideline 875.2100.

I.   MATERIALS AND METHODS

A.   MATERIALS:

1.   Test Material:

Formulation: SYN545377 WG (40) is formulated as a water-dispersible granule containing
                                40.7% active ingredient, cyantraniliprole.
Batch/Lot #:   573064 (formulated product)
Formulation guarantee: The Study Report stated that the test product contained 40.7% cyantraniliprole
                                (assayed on July 14, 2009). Expiration date: July, 2012.
Purity: The cyantraniliprole reference standard was analyzed and found to have a purity
                                of 99.2%. Expiration date: September, 2015.
CAS #:   736994-63-1
Other Relevant Information: None.

2. **Relevance of Test Material to Proposed Formulation(s):**

The test product used in this study was the proposed water-dispersible granule formulation, SYN545377 WG (40), containing 40.7% cyantraniliprole which will reportedly be used for systemic control of insect pests on potatoes, vegetable crops and ornamental plants. This is protective of several proposed application rates of various formulations for use on peppers (ranging from 10.2-20.0%)

B. **STUDY DESIGN:**

The study protocol was provided with the Study Report and there three amendments to the protocol and three reported protocol deviations. The three protocol amendments addressed issues such as: (1) listing the procedures for generating control pepper dislodging sample by the laboratory for method validation purposes; (2) reporting a change with the Sponsor Representative/Study Monitor; (3) reporting that tank mix samples were not analyzed; (4) adding schedule flexibility to the FPI; (5) reporting that sample storage stability was not in question since the samples were analyzed within 30 days of collection; and (6) adding 28- and 35-day sampling intervals to the CA trial because the residues had not declined to non-quantifiable levels by Day 21. The protocol deviations involved: (1) applications were 6 days apart instead of 5 days apart at the PA site; (2) the Day 1 samples for the GA site were not collected due to Field Investigator oversight; and (3) sets 3 and 8 did not contain enough fortifications for a 20% ratio to the treated samples due to Lead Chemist oversight. The study author reported that none of the reported deviations had a negative impact on the validity or integrity of the study.

1. **Site Description:**

Test locations: The DFR portion of the study was conducted at three locations: Germansville, Lehigh County, PA (Site 01); Chula, Tift County, GA (Site 02); and Fresno, Fresno County, CA (Site 03). The test sites were said to be representative of typical growing areas for peppers. One control plot and one treated plot were established at the test sites. According to the plot diagrams, buffer zones ranging from 235 to 420 ft were established between the control and treated plots.

Areas sprayed and sampled: PA Site: 1875 ft^2 (0.043 acre) were treated.
GA Site: 1875 ft^2 (0.043 acre) were treated.
CA Site: 2000 ft^2 (0.046 acre) were treated.

Meteorological Data: Daily maximum and minimum air temperatures, average relative humidity, wind speed, predominant wind direction, rainfall and irrigation were reportedly recorded for each test site, however this information was not provided in the report. Meteorological data were obtained from the test site, the nearest NOAA or other permanent weather recording stations. In addition, the most recent historical average 10-year minimum and maximum air temperature and precipitation data were collected from the nearest weather recording station. Relative humidity was only reported for the time nearest to each application time for each test site. Wind speed and direction were not provided in the report for any of the three test sites.

At the PA site, daily meteorological data were obtained from onsite equipment. Current temperatures and rainfall were slightly higher than reported historical maximum values. The plots were irrigated one day before and the day of the third application for two and five hours, respectively, by drip irrigation.

At the GA site, daily meteorological data were obtained from onsite equipment. Current temperatures were slightly higher than reported historical maximum values. Rainfall was lower than the historical average. The plots were irrigated every other day for two hours by drip irrigation.

At the CA site, daily meteorological data were obtained from CIMIS #80, located approximately 14 miles from the test site. Current temperatures and rainfall totals were similar to the reported historical data. There was no recorded rainfall event at this test site for the duration of the field phase of the study; however, the plots were irrigated 12 hours per week by drip irrigation.

2. **Crop Characteristics:**

Crop, variety: PA Site: Pepper, Red Knight, planted June 15, 2010.
                        GA Site: Pepper, Bonnie Green Bell, planted April 30, 2010.
                        CA Site: Pepper, Baron, planted April 28, 2010.

Row width, plant spacing: Row width and plant spacing were not reported for any of the three test sites.

Stage of growth: PA Site: All three applications were made at fruit set and when plants were 12 to 40 inches in height.
                        GA Site: All three applications were made at flowers to small fruit and when plants were 10 to 18 inches in height.
                        CA Site: All three applications were made when the fruit on the main stem were at the typical size and form (BBCH 71) and when plants were 8 to 12 inches in height.

Other products used on crop: The test products were grown and maintained according to typical agricultural practices. There were no maintenance chemicals applied during the field trial phase of the study at the PA and CA sites. Two maintenance chemicals were applied to the test plot at the GA site (Ignite and Gramoxone Inteon) on the day of the first application.

3. **Application Rates and Regimes**:

Application rate(s):   The target application rate was made up of three foliar broadcast applications at 0.134 lb ai/A (150 g ai/ha) per application for a total application rate of 0.402 lb ai/A (450 g ai/ha) per season. No surfactants were added to the tank mixes. According to the report, the application rate used in this study is the proposed maximum label rate for use on peppers.

PA Site: The actual application rates for all three applications were 0.136, 0.137 and 0.134 lb ai/A for a total seasonal application rate of 0.407 lb ai/A. These application rates were 100 to 102% of the target application rate.

GA Site: The actual application rates for all three applications were 0.137, 0.135 and 0.138 lb ai/A for a total seasonal application rate of 0.410 lb ai/A. These application rates were 101 to 103% of the target application rate.

CA Site: The actual application rate was 0.135 lb ai/A for all three applications for a total seasonal application rate of 0.405 lb ai/A. These application rates were 101% the target application rate.

Application Regime: Each treated plot received three hand boom applications 5 ± 1 days apart. The spray mix was prepared on the day of application at each site using water as the carrier. The spray mix included extra volume to maintain spray system prime and to avoid running out of mix while spraying the plots. The spray nozzles were configured in a typical boom spray pattern with individual nozzles positioned perpendicular to the boom.

Application Equipment: PA Site: The test substance was applied using a CO_2 backpack boom sprayer with 3 hollow cone nozzles (TSS-SX18 Cone Jet) spaced 20 inches apart. The sprayer swath width was 5 ft.

GA Site: The test substance was applied using a CO_2 backpack boom sprayer with 5 flat fan nozzles spaced 18 inches apart. The sprayer swath width was 7.5 ft.

CA Site: The test substance was applied using a CO2 backpack boom sprayer with 3 TeeJet flat fan (8003XR) nozzles spaced 20 inches apart. The sprayer swath width was 5 ft.

Spray Volume: The targeted spray volume was 2 to 50 gallons per acre (GPA) total aqueous spray mixture. Rate verification from in-field measurements showed that volumes were within the target at all three trials.

PA Site: A spray volume of 45 GPA was used for each application.

GA Site: A spray volume of 24.6 to 24.7 GPA was used for the three applications at this site.

CA Site: A spray volume of 30 GPA was used for the three applications.

Equipment Calibration Procedures: The same calibration procedures were used at all three sites. The actual nozzle output for three catches with catch times of at least 30 seconds or greater were recorded and averages for each nozzle were determined as well as an overall mean for the boom. The boom delivery per second based on the total boom output and catch times were then calculated.

4. **Dislodgeable Foliar Residue Sampling Procedures**:

Method and Equipment: DFR samples consisted of 40 leaf disks which were collected with a leaf puncher (1-inch diameter).

Sampling Procedure: Leaf punch samples were collected by hand using two leaf punch samplers (one for the treated plot and one for the control plot). The untreated plot was sampled before the treated plot, unless two people were sampling the two plots at the same time. Leaf punches were collected directly into clean, pre-labeled glass jars. Leaf punches were collected randomly throughout each replicate. All leaf punches were collected when the foliage was dry. The leaves selected for sampling were healthy and mature. Once a leaf was sampled, the same leaf was not sampled again for the duration of the trial.

Total Surface Area per Replicate: The double sided surface area per leaf punch was approximately 10 cm^2. The total surface area of each sample was 400 cm^2.

Replicates per activity:
    – Replicates per sampling time: At each sampling interval for the treated plot, triplicate DFR samples were collected. One sample was collected at each sampling interval for the control plot.

    – Number of sampling times: There were a total of 12, 10, and 14 sampling events were made at the PA, GA, and CA sites, respectively. One sample was collected prior to the first application at the PA and CA sites.

Times of sampling: At the PA site, samples were collected before each application, at 0 hours after each application (when dry), at 6 hours after the third application, and at 1, 2, 4, 7, 10, 15, and 21 days after the third application. At the GA site, samples were collected at 7.5 hours, 2, 4, 7, 10, 14, and 21 days after the third application. At the CA site, samples were collected at the same time intervals as the PA site, with 14 day sampling instead of 15 day, and the addition of 29- and 35-day sampling intervals.

Part(s) of foliage sampled: The pepper leaves were large enough to accommodate a 1-inch leaf punch. The leaf punches were taken from mature leaves, along the midrib towards the tip of the leaf.

5. **Sample Handling:**

The field phase of this study began on July 2, 2010 and the last sampling event took place on August 30,

2010. According to the Study Report, samples were stored in coolers with ice or ice substitute and then taken to the dislodging area. Dislodging was performed within 3 hours after sample collection. The dislodged samples were maintained frozen at the field facilities until they were shipped via freezer truck to ABC Laboratories, Inc. located in Columbia, Missouri for analysis. During storage, temperatures ranged from -26°C to -4°C (-15°F to 24°F). Field samples were shipped from each test site overnight to the analytical laboratory via FedEx in coolers packed with dry ice. The field samples from the PA site were shipped on August 10, 17, and 31, 2010. Field samples from the GA site were shipped on July 12, 19, and 26 and August 4, 2010. Field samples from the CA site were shipped on July 13, 21, and 28 and August 4, and 18, 2010. The analytical phase of the study started on July 14, 2010 and the last field sample was analysed on September 3, 2010. The maximum length of frozen storage for the treated samples from sample collection to sample analysis was 21 days for the PA site, 18 days for the GA site, and 28 days for the CA site. The maximum length of frozen storage for the field fortification samples was 21 days for the PA site, 50 days for the GA site, and 49 days for the CA site.

6. **Analytical Methodology:**

Dislodging solution:	Cyantraniliprole residues were dislodged twice using 0.01% Aerosol® OT solution.
Dislodging procedure:	Samples were dislodged within the sampling jars twice. Each dislodging used 100 mL of the 0.01% Aerosol OT solution. Dislodging was conducted by shaking the sample on a mechanical shaker for 10 minutes. The resulting solutions (2 dislodgings) were combined and the foliage was discarded. Following dislodging, aliquots were placed into pre-labeled polypropylene tubes with screw caps, taped to prevent leaking. The tubes were then placed into Ziploc bags and immediately placed into a freezer at about a 45° angle until frozen.

Time interval (sample collection to dislodging): Samples were dislodged within 3 hours of collection.

Extraction method: DFR samples were thawed and then shaken vigorously to ensure a homogenous sample. An aliquot of the dislodged solution was diluted with an appropriate amount of 50:50 methanol:water and analyzed without any further clean up. This diluted extract was transferred to an HPLC vial for analysis.

Detection methods: All samples were analyzed using ultra high pressure liquid chromatography (UPLC) with Turbo IonSpray (TIS) in positive mode. A summary of the UPLC-TIS conditions are shown in Table 1.

Table 1. Summary of Typical UPLC-TIS Conditions	
UPLC Conditions	
System:	MDS Sciex API 5000 LC-MS/MS; Waters Acquity UPLC System
Column:	Synergi 2.5 μm Polar RP, 50 x 3.00 mm
Column Temperature:	30 ^{o}C
Injection Volume:	3 μL
Autosampler Temperature:	10 ^{o}C
Flow Rate:	0.50 mL/minute
Conditions:	A: 0.1% Formic Acid in Water B: 0.1% Formic Acid in Methanol Time %A %B 0.0 50.0 50.0 3.0 30.0 70.0 6.0 30.0 70.0 7.0 5.0 95.0 8.0 5.0 95.0 8.1 50.0 50.0 10.0 50.0 50.0
Approximate Retention Time:	2.9 minutes for Cyantraniliprole
Total Run Time:	10.0 minutes
TIS-LC-MS/MS Ion Mode:	MRM
Ions Monitored:	475 → 286 AMU

Method validation: The analytical method was developed and validated by ABC Laboratories prior to analysis of the samples using control pepper leaf disc wash dislodgeable solutions. The results from the method validation verified the integrity and efficiency of the method used for analysis of cyantraniliprole. Dislodging solutions were fortified at three levels (0.005, 0.025, and 0.250 μg/cm^2). The overall mean recovery was 104% (n=9). The validated limit of quantitation (LOQ) was 0.005 μg/cm^2; the limit of detection (LOD) was 0.0015 μg/cm^2.

Instrument performance: A series of calibration standards ranging from 0.2 to 10 ng/mL of cyantraniliprole were injected with each set to quantify residues in the samples. These calibration standards generated a linear plot of cyantraniliprole that yielded correlation coefficients equal to or greater than 0.999 (r^2 equal to or greater than 0.99).

Quantification: Quantitation of residues in all samples was achieved by using a calibration curve calculated by linear regression of instrument responses for each of the reference substances at multiple concentrations.

7. <u>Quality Control</u>:

Lab Recovery: Concurrent laboratory fortified samples were analyzed with each set of field samples. Control 0.01% AOT samples were fortified with cyantraniliprole at concentrations ranging from 0.005 to 0.700 $\mu g/cm^2$. Individual concurrent laboratory recoveries ranged from 70.8% to 114% with an overall mean recovery of 94% $\pm$ 11.7% (n= 17).

Field blanks: One control sample was collected at each time the control plot was sampled. Fifteen untreated control dislodging solution samples were analyzed. No cyantraniliprole residues were detected or were any analytical interferences present.

Field recovery: Triplicate field-fortified samples were prepared three times during the study at each site using samples from the control plot at two fortification levels (0.025 $\mu g/cm^2$ and 0.25 $\mu g/cm^2$) to evaluate the stability of the field samples during shipping and storage. For the PA site, the field-fortified samples were prepared on the day of the first application (pre-application), on the day before the third application, and on Day 10 after the third application. For the GA site, the field fortification samples were prepared one day before the first application, on the day of the third application (pre-application), and on Day 10 after the third application. For the CA site, the field-fortified samples were prepared on the day of the first application (pre-application), on the day of the third application (pre-application), and on Day 10 after the third application. The field fortified samples were shipped and stored in the freezer under the same conditions as the field samples for up to 50 days.

Table 2 provides a summary of the field fortification recoveries. The overall mean field fortification recoveries for the PA, GA, and CA sites were 97.4% $\pm$ 4.16%, 94.6% $\pm$ 10.8%, and 91.6% $\pm$ 7.89%, respectively.

Cyantraniliprole/PC Code: 090098   **Dislodgeable Foliar Residues/**OPPTS 875.2100

Sampling Event	Nominal Fortification Level (ppm)	Cyantraniliprole Residue (ppm)	Percent Recovery (%)	Average Percent Recovery per Level (%)	Overall Low Level Percent Recovery (%)	Overall High Level Percent Recovery (%)	Overall Percent Recovery (%)	Std. Dev.
Table 2. Summary of Field Fortification Recoveries									
PA Site									
-0DAT1	0.05	0.049	98.6	100				
	0.05	0.050	101					
	0.05	0.051	102					
	0.50	0.472	94.5	97.9				
	0.50	0.490	98.0					
	0.50	0.507	101					
-1DAT3	0.05	0.048	96.4	97.7	97.4	97.3	97.4	4.16
	0.05	0.048	96.4					
	0.05	0.050	100					
	0.50	0.464	92.7	96.0				
	0.50	0.483	96.7					
	0.50	0.493	98.5					
10DAT3	0.05	0.042	84.4	94.3				
	0.05	0.049	97.4					
	0.05	0.051	101					
	0.50	0.488	97.7	97.9				
	0.50	0.506	101					
	0.50	0.474	94.8					
GA Site									
-1DAT1	0.05	0.045	90.0	89.7				
	0.05	0.049	97.6					
	0.05	0.041	81.6					
	0.50	0.500	99.9	99.6				
	0.50	0.488	97.5					
	0.50	0.506	101					
-0DAT3	0.05	0.047	93.6	93.5	92.6	96.5	94.6	10.8
	0.05	0.049	97.2					
	0.05	0.045	89.8					
	0.50	0.553	111	90.0				
	0.50	0.500	100					
	0.50	0.297	59					
10DAT3	0.05	0.046	92.2	94.7				
	0.05	0.050	99.6					
	0.05	0.046	92.2					
	0.50	0.512	102	100				
	0.50	0.493	98.5					
	0.50	0.495	99.0					
CA Site									
-0DAT1	0.05	0.047	93.2	89.3				
	0.05	0.042	83.0					
	0.05	0.046	91.8					
	0.50	0.498	99.6	88.4	90.6	92.7	91.6	7.89
	0.50	0.485	96.9					
	0.50	0.343	68.6					
-0DAT3	0.05	0.044	87.0	91.0				
	0.05	0.046	91.8					

Sampling Event	Nominal Fortification Level (ppm)	Cyantraniliprole Residue (ppm)	Percent Recovery (%)	Average Percent Recovery per Level (%)	Overall Low Level Percent Recovery (%)	Overall High Level Percent Recovery (%)	Overall Percent Recovery (%)	Std. Dev.
	0.05	0.047	94.2					
	0.50	0.483	96.5					
	0.50	0.491	98.2	92.2				
	0.50	0.409	81.9					
	0.05	0.045	90.2					
	0.05	0.045	89.0	91.4				
3DAT3	0.05	0.048	95.0					
	0.50	0.459	91.9					
	0.50	0.505	101	97.5				
	0.50	0.498	99.6					

Table 2. Summary of Field Fortification Recoveries

Formulation: SYN545377 WG is a water-dispersible granular formulation containing 40.7% active ingredient, cyantraniliprole.

Tank mix: Tank mix samples were not collected for this study.

Travel Recovery: Travel recovery samples were not used in this study.

Storage Stability: A frozen storage stability study of cyantraniliprole residues in pepper leaf DFR dislodging solutions was not performed for this study. All of the field samples were analysed within 30 days of collection. The maximum length of frozen storage for the treated samples from sample collection to sample analysis was 21 days for the PA site, 18 days for the GA site, and 28 days for the CA site. The maximum length of frozen storage for the field fortification samples was 21 days for the PA site, 50 days for the GA site, and 49 days for the CA site.

II. RESULTS AND CALCULATIONS

The Registrant provided DFRs in $\mu g/cm^2$. The Registrant and HED corrected the residue data for the corresponding average field fortification recoveries. The residue data from the PA test site were corrected for overall average low and high level field fortification recoveries of 97.4% and 97.3%, respectively. The residue data from the GA test site were corrected for overall average low and high level field fortification recoveries of 92.6% and 96.5%, respectively. The residue data from the CA test site were corrected for overall average low and high level field fortification recoveries of 90.6% and 92.7%, respectively.

At the PA site, the highest average DFR value occurred immediately after the third application, 0DAT3 (0.449 $\mu g/cm^2$ or 29.9% of the application rate), and dropped to 0.014 $\mu g/cm^2$ by 21DAT3.

At the GA site, the highest average DFR value occurred immediately after the third application, 0DAT3 (0.435 $\mu g/cm^2$ or 28.1% of the application rate), and dropped to below the LOQ (0.004 $\mu g/cm^2$) by 14DAT3.

At the CA site, the highest average DFR value occurred immediately after the third application, 0DAT3 (0.716 $\mu g/cm^2$ or 47.3% of the application rate), and dropped to 0.046 $\mu g/cm^2$ by 35DAT3.

The Registrant generated decline curves using the natural log-transformation (ln) of the residues to generate a log-linear graph and a simple regression equation based on a one compartment model. The Registrant's calculated half-lives for cyantraniliprole pepper leaf tissue were 3.9 days ($R^2 = 0.922$) for the PA site, 2.8 days ($R^2 = 0.812$) for the GA site, and 8.4 days ($R^2 = 0.953$) for the CA site.

First-order dissipation kinetics were used to generate dissipation curves for cyantraniliprole. The linear regression analysis was conducted using the natural logarithm of the individual foliar residue values collected immediately after the application through 21DAT3 for the PA and GA sites and 35DAT3 for the CA site. The GA site was the only site where all residues dropped below the LOQ 0.005 µg/cm^2 by the last sampling interval (21DAT3). Based on linear regression of the natural log transformed data, the calculated half-lives for cyantraniliprole pepper leaf tissue were 3.8 days ($R^2 = 0.921$) for the PA site, 2.9 days ($R^2 = 0.842$) for the GA site, and 8.4 days ($R^2 = 0.932$) for the CA site.

Tables 3 through 5 provide a summary of the cyantraniliprole DFR values and calculated statistical summaries. A graphical representation of cyantraniliprole residue dissipation after treatment is presented in Figure 1. Table 6 provides a summary of the regression statistics for all three test sites.

III DISCUSSION:

A. LIMITATIONS OF THE STUDY:

This study met the majority of the Series 875.2100 Guidelines. The following issues of concern are noted:

- Rainfall appears to be an issue at the Georgia test site. The executive summary of the study report states that the sample which should have been collected 6 hours after the third application was not collected due to rainfall. The sample was collected 1.5 hours later at 7.5 hours after application (when the leaves were dry). It appears from the statement in the executive summary that rain fell immediately after the application potentially washing off the residues. Daily rainfall events were not documented in the study report.

- The Registrant validated the analytical method using samples fortified at levels ranging from 0.005 and 0.250 µg/cm^2. The field fortification levels were 0.025 and 0.250 µg/cm^2. These levels do not bracket the range of field sample residue levels from any of the three test sites. Individual field sample residues ranged from 0.008 to 0.766 µg/cm^2.

- Daily meteorological data were reportedly collected, but were not provided for any of the test sites for the duration of the study. Only monthly maximum and minimum temperatures and total monthly precipitation data were provided for the duration of the study. Relative humidity was provided for the day of the applications; however, wind direction/velocity, rainfall and cloud cover was not provided for any of the test sites for application day.

- The production of metabolites, breakdown products, or the presence of contaminants of concern were not discussed in the Study Report.

- Tank mix samples were not collected after application to check for uniformity.

B. CONCLUSIONS:

There was a rapid decline of the cyantraniliprole DFR at all test sites over time. The half-life values

calculated by the Registrant were very similar to those calculated by HED. The calculated half-life value for the CA test site was significantly different from that at the PA and GA test sites. The Registrant stated that the relatively slower decline of the DFR of cyantraniliprole at the CA site versus the PA and GA test sites could be due to the absence of rainfall at the CA test site. Cyantraniliprole is known to dissipate more rapidly in water. Drip irrigation was applied to the roots of the pepper plants only.

Table 3. Cyantraniliprole DFR Residues from Pepper Plants Treated with SYN545377 40WG – PA Site						
Sample Interval	Corrected Cyantraniliprole Residue (μg/cm^2)	Arithmetic Mean (μg/cm^2)	Standard Deviation (μg/cm^2)	Coefficient of Variance (%)	Natural Log of Mean (μg/cm^2)	Percent of Original Application Rate Dislodgeable
Post-App 1	0.298	0.277	0.045	16.2	-1.28	18.2
	0.308					
	0.226					
Pre-App 2	0.049	0.063	0.012	18.47	-2.77	4.11
	0.069					
	0.070					
Post-App 2	0.391	0.367	0.033	9.01	-1.00	23.9
	0.380					
	0.329					
Pre-App 3	0.308	0.267	0.037	14.0	-1.32	17.4
	0.257					
	0.236					
Post-App 3	0.401	0.449	0.058	13.0	-0.801	29.9
	0.514					
	0.432					
0.25DAT3	0.401	0.439	0.049	11.1	-0.824	29.2
	0.421					
	0.493					
1DAT3	0.432	0.432	0.062	14.3	-0.840	28.7
	0.370					
	0.493					
2DAT3	0.401	0.415	0.033	7.97	-0.880	27.6
	0.452					
	0.391					
4DAT3	0.113	0.123	0.010	8.33	-2.09	8.20
	0.123					
	0.133					
7DAT3	0.075	0.064	0.014	21.8	-2.75	4.26
	0.069					
	0.048					
10DAT3	0.047	0.060	0.011	19.2	-2.82	3.96
	0.070					
	0.062					
14DAT3	0.024	0.028	0.004	14.8	-3.59	1.84
	0.028					
	0.032					

	0.018					
21DAT3	0.009	0.014	0.005	36.1	-4.30	0.900
	0.013					

Notes:
Test product used at the site was cyantraniliprole 40WG.
DAT = Day after Treatment
LOQ = 0.005 µg/cm^2 and LOD = 0.0015 µg/cm^2
DFRs were corrected for corresponding average low or high level field fortification recoveries of 97.4% and 97.3%, respectively.
Percent of Original Application Rate Dislodgeable = DFR (µg/cm^2) / Amount applied (µg/cm^2) x 100%

Table 4. Cyantraniliprole DFR Residues from Pepper Plants Treated with SYN545377 40WG – GA Site						
Sample Interval	Corrected Cyantraniliprole Residue (µg/cm^2)	Arithmetic Mean (µg/cm^2)	Standard Deviation (µg/cm^2)	Coefficient of Variance (%)	Natural Log of Mean (µg/cm^2)	Percent of Original Application Rate Dislodgeable
Post-App 1	0.363	0.345	0.022	6.24	-1.063	22.5
	0.321					
	0.352					
Pre-App 2	0.064	0.071	0.011	15.5	-2.652	4.59
	0.083					
	0.065					
Post-App 2	0.425	0.404	0.027	6.78	-0.906	26.7
	0.414					
	0.373					
Pre-App 3	0.070	0.080	0.009	10.7	-2.53	5.28
	0.083					
	0.086					
Post-App 3	0.404	0.435	0.045	10.4	-0.832	28.1
	0.414					
	0.487					
0.313DAT3	0.049	0.064	0.014	22.3	-2.75	4.14
	0.077					
	0.067					
2DAT3	0.045	0.054	0.008	14.4	-2.92	3.49
	0.060					
	0.056					
4DAT3	0.032	0.041	0.013	32.0	-3.19	2.65
	0.056					
	0.035					
7DAT3	0.017	0.017	0.001	3.69	-4.08	1.09
	0.016					
	0.017					
10DAT3	0.009	0.015	0.006	41.5	-4.19	0.984
	0.022					
	0.015					
14DAT3	<LOQ	0.004	0.004	102	-5.57	0.247
	0.008					
	<LOD					
21DAT3	<LOQ	0.001	0.001	75.8	-6.62	0.086
	<LOD					
	<LOD					

Notes:
Test product used at the site was cyantraniliprole 40WG.

DAT = Day after Treatment
LOQ = 0.005 μg/cm^2 and LOD = 0.0015 μg/cm^2
½ LOQ was used for calculation purposes when residue values were below the LOQ and ½ LOD was used when residues were below the LOD.
DFRs were corrected for corresponding average low or high level field fortification recoveries of 92.6% and 96.5%, respectively.
Percent of Original Application Rate Dislodgeable = DFR (μg/cm^2) / Amount applied (μg/cm^2) x 100%

Table 5. Cyantraniliprole DFR Residues from Pepper Plants Treated with SYN545377 40WG – CA Site						
Sample Interval	Corrected Cyantraniliprole Residue (μg/cm^2)	Arithmetic Mean (μg/cm^2)	Standard Deviation (μg/cm^2)	Coefficient of Variance (%)	Natural Log of Mean (μg/cm^2)	% of Original App Rate Dislodgeable
Post-App 1	0.367	0.370	0.016	4.45	-0.993	24.5
	0.356					
	0.388					
Pre-App 2	0.232	0.258	0.023	8.92	-1.36	17.0
	0.276					
	0.265					
Post-App 2	0.561	0.557	0.070	12.6	-0.584	36.8
	0.486					
	0.626					
Pre-App 3	0.378	0.399	0.022	5.41	-0.918	26.4
	0.421					
	0.399					
Post-App 3	0.669	0.716	0.049	6.80	-0.334	47.3
	0.766					
	0.712					
0.25DAT3	0.561	0.615	0.067	11.0	-0.486	40.6
	0.593					
	0.691					
1DAT3	0.658	0.698	0.035	4.97	-0.360	46.1
	0.712					
	0.723					
2DAT3	0.626	0.658	0.066	10.0	-0.418	43.5
	0.615					
	0.734					
4DAT3	0.572	0.629	0.050	7.92	-0.463	41.6
	0.658					
	0.658					
7DAT3	0.486	0.507	0.022	4.26	-0.679	33.5
	0.529					
	0.507					
10DAT3	0.265	0.354	0.078	22.1	-1.04	23.4
	0.410					
	0.388					
14DAT3	0.265	0.329	0.058	17.6	-1.11	21.8
	0.345					
	0.378					
21DAT3	0.110	0.195	0.075	38.5	-1.63	12.9
	0.254					
	0.221					
29DAT3	0.040	0.050	0.015	29.4	-2.99	3.33
	0.067					
	0.044					

	0.031					
35DAT3	0.065	0.046	0.018	38.6	-3.09	3.02
	0.041					

Notes:
Test product used at the site was cyantraniliprole 40WG.
DAT = Day after Treatment
LOQ = 0.005 µg/cm^2 and LOD = 0.0015 µg/cm^2
DFRs were corrected for corresponding average low or high level field fortification recoveries of 90.6% and 92.7%, respectively.
Percent of Original Application Rate Dislodgeable = DFR (µg/cm^2) / Amount applied (µg/cm^2) x 100%

Table 6. Regression Summary for Pepper Leaves Treated with Cyantraniliprole 40% WDG			
Statistic	PA site	GA site	CA site
Measured Day 0 DFR (average) (µg/cm^2)	0.449	0.435	0.716
Predicted Day 0 DFR (µg/cm^2)	0.398	0.123	0.793
Slope	-0.181	-0.242	-0.083
Half-life (days)	3.8	2.9	8.45
R^2	0.921	0.842	0.932

Note: Rainfall immediately after the third application has potentially washed off residues at the GA test site. Predicted Day 0 levels are much lower than actual measured Day 0 levels. Regressions are based on data collected after third application.

Figure 1. Dislodged Cyantraniliprole Residues from Treated Pepper Leaves
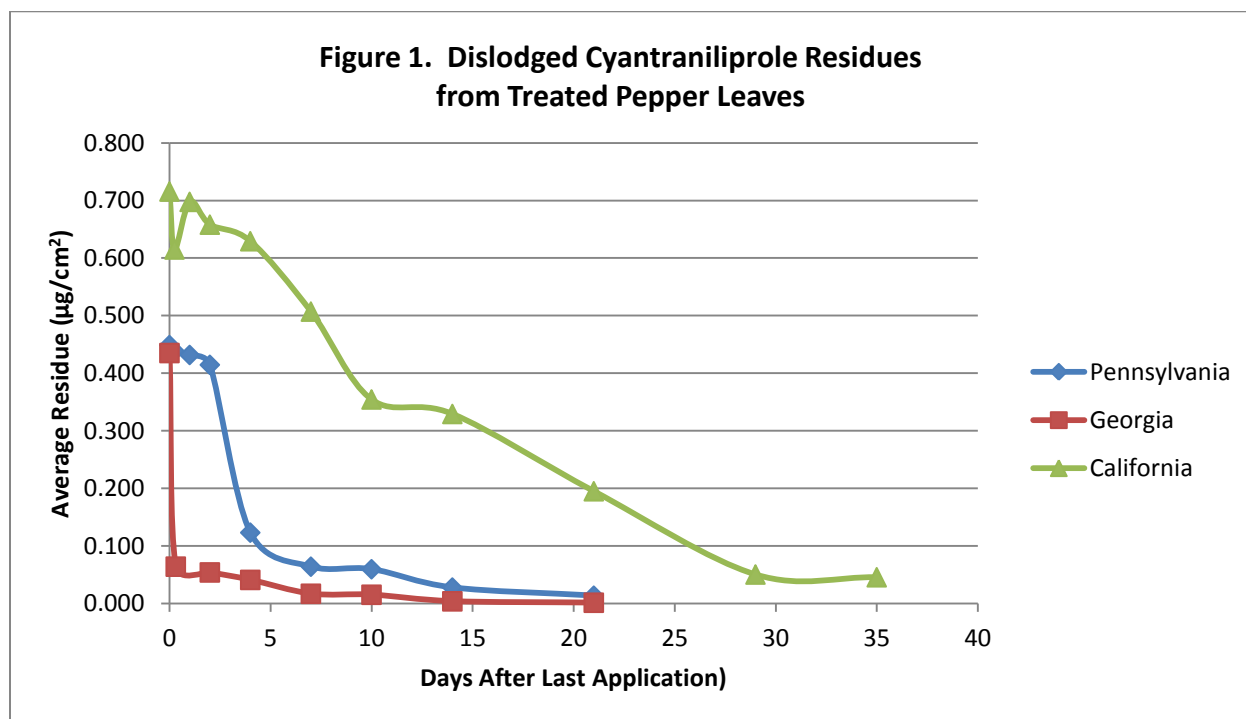
APPENDIX A. Regression Analysis Results

Regression Analysis: Summary Output for Pennsylvania Pepper Leaves

Regression Statistics	
Multiple R	0.959458
R Square	0.92056
Adjusted R^2	0.917383
Standard Error	0.376034
Observations	27

ANOVA

	df	SS	MS	F	Signif. F
Regression	1	40.96466	40.96466	289.70427	2.92207E-15
Residual	25	3.535041	0.141402		
Total	26	44.4997			

	Coeff.	Std. Error	t Stat	P-value	Lower 95%	Upper 95%
Intercept	-0.92037	0.100677	-9.14184	1.899E-09	-1.127722881	-0.713025928
Slope	-0.18096	0.010632	-17.0207	2.922E-15	-0.20285346	-0.159061083

Half Life =   3.830447   Days

Predicted DFR Levels

Time (Days)	Residue (ug/cm2)	Time (Days)	Residue (ug/cm2)
0	0.39837	21	0.0089109
1	0.332428	22	0.0074359
2	0.277402	23	0.0062051
3	0.231484	24	0.0051779
4	0.193166	25	0.0043208
5	0.161192	26	0.0036056
6	0.13451	27	0.0030088
7	0.112245	28	0.0025107
8	0.093665	29	0.0020951
9	0.078161	30	0.0017483
10	0.065223	31	0.0014589
11	0.054426	32	0.0012174
12	0.045417	33	0.0010159

13	0.037899	34	0.0008478
14	0.031626	35	0.0007074
15	0.026391		
16	0.022022		
17	0.018377		
18	0.015335		
19	0.012797		
20	0.010679		

Regression Analysis: Means and CVs for Pennsylvania Pepper Leaves

Days after Last Treatment	Residues (ug/cm2)	Mean (ug/cm2)	Standard Deviation (ug/cm2)	Coefficient of Variation (%)
0	0.401	0.449	0.0585	13
	0.514			
	0.432			
0.25	0.401	0.439	0.0486	11.1
	0.421			
	0.493			
1	0.432	0.432	0.0617	14.3
	0.370			
	0.493			
2	0.401	0.415	0.033	7.96
	0.452			
	0.391			
4	0.113	0.123	0.0103	8.34
	0.123			
	0.133			
7	0.075	0.064	0.014	21.8
	0.069			
	0.048			
10	0.047	0.0595	0.0114	19.2
	0.070			
	0.062			
14	0.024	0.0277	0.0041	14.8
	0.028			
	0.032			
21	0.018	0.0135	0.00488	36.1
	0.009			
	0.013			

Regression Analysis: Log of Dislodgeable Foliar Residue vs. Time for Pennsylvania Pepper Leaves
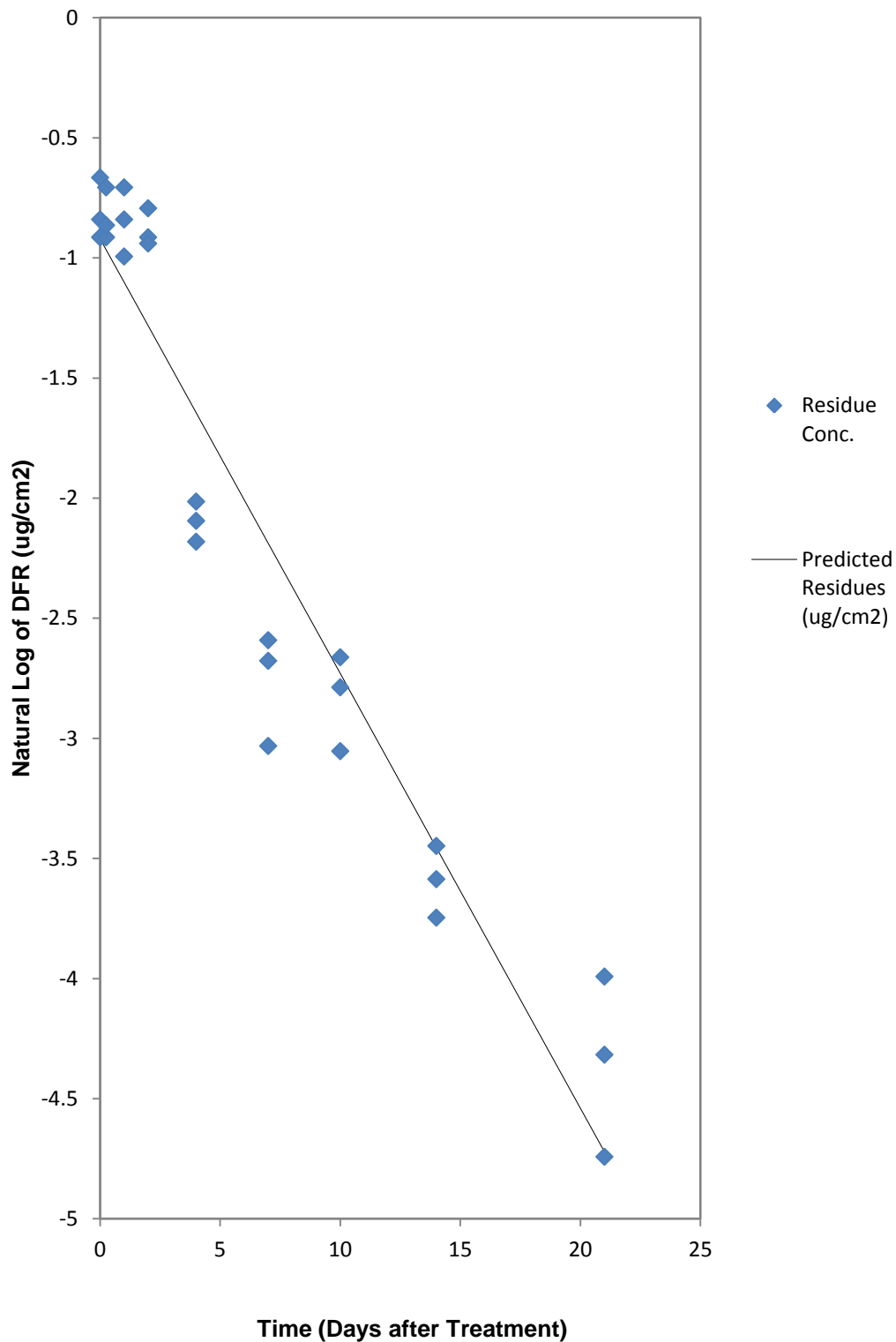
Regression Analysis: Summary Output for Georgia Pepper Leaves

Regression Statistics	
Multiple R	0.917805
R Square	0.842366
Adjusted R^2	0.835201
Standard Error	0.754988
Observations	24

ANOVA

	df	SS	MS	F	Signif. F
Regression	1	67.012	67.012	117.56361	2.71564E-10
Residual	22	12.54014	0.570006		
Total	23	79.55214			

	Coeff.	Std. Error	t Stat	P-value	Lower 95%	Upper 95%
Intercept	-2.09419	0.22415	-9.34281	4.097E-09	-2.55904887	-1.629331642
Slope	-0.24212	0.02233	-10.8427	2.716E-10	-0.288427241	-0.195807842

Half Life =   2.862854   Days

Predicted DFR Levels

Time (Days)	Residue (ug/cm2)	Time (Days)	Residue (ug/cm2)
0	0.12317	21	0.0007627
1	0.096684	22	0.0005987
2	0.075893	23	0.0004699
3	0.059574	24	0.0003689
4	0.046763	25	0.0002896
5	0.036707	26	0.0002273
6	0.028814	27	0.0001784
7	0.022618	28	0.0001401
8	0.017754	29	0.0001099
9	0.013936	30	8.63E-05
10	0.01094	31	6.774E-05
11	0.008587	32	5.317E-05
12	0.006741	33	4.174E-05
13	0.005291	34	3.276E-05

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14	0.004153	35	2.572E-05
15	0.00326		
16	0.002559		
17	0.002009		
18	0.001577		
19	0.001238		
20	0.000972		

Regression Analysis: Means and CVs for Georgia Pepper Leaves

Days after Last Treatment	Residues (ug/cm2)	Mean (ug/cm2)	Standard Deviation (ug/cm2)	Coefficient of Variation (%)
0	0.404	0.435	0.0452	10.4
	0.414			
	0.487			
0.313	0.049	0.064	0.0143	22.3
	0.077			
	0.067			
2	0.045	0.054	0.00778	14.4
	0.060			
	0.056			
4	0.032	0.041	0.0131	32
	0.056			
	0.035			
7	0.017	0.0169	0.000623	3.69
	0.016			
	0.017			
10	0.009	0.0152	0.00632	41.5
	0.022			
	0.015			
14	0.003	0.00382	0.0039	102
	0.008			
	0.001			
21	0.003	0.00133	0.00101	76
	0.001			
	0.001			

Regression Analysis: Log of Dislodgeable Foliar Residue vs. Time for Georgia Pepper Leaves
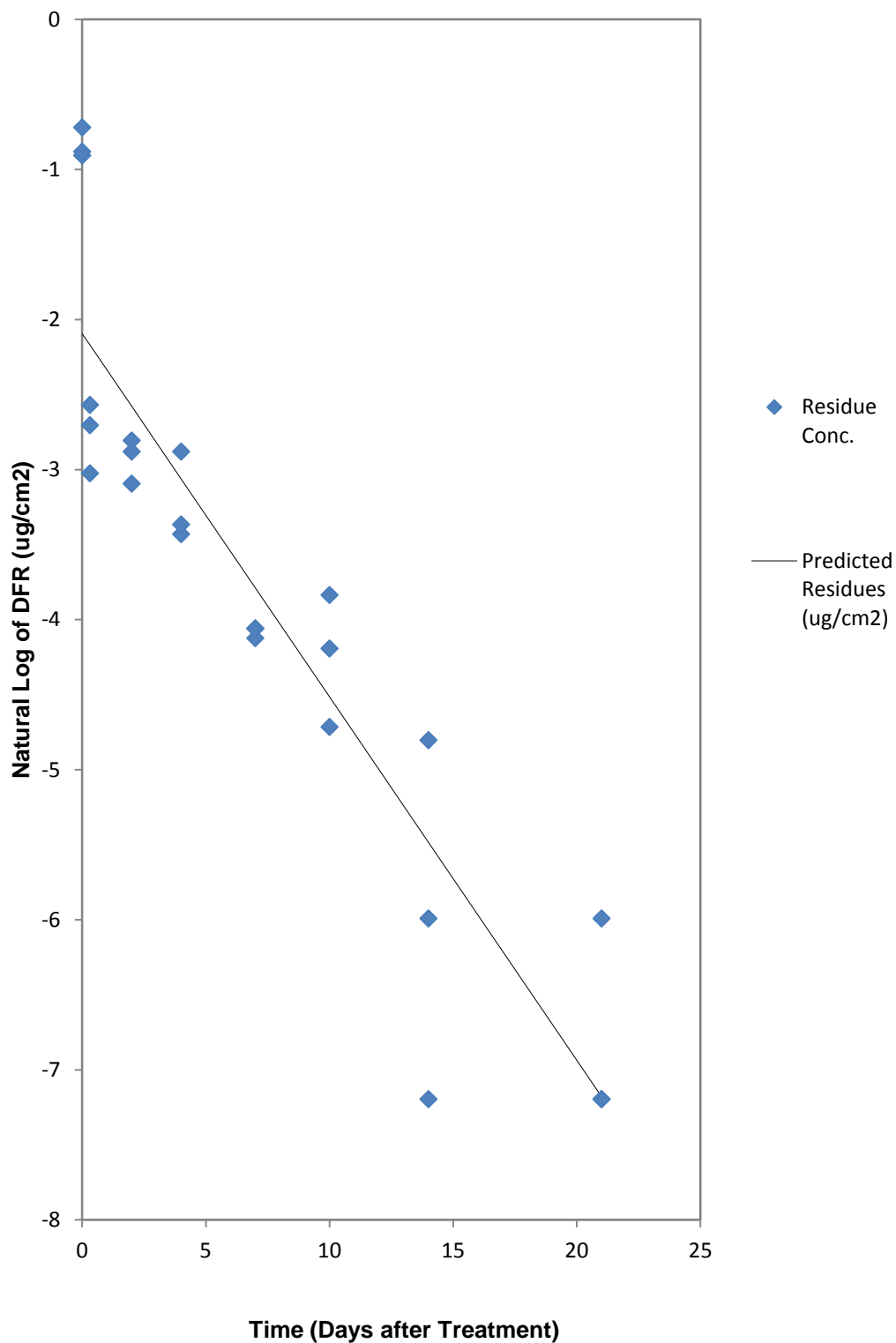
Regression Analysis: Summary Output for California Pepper Leaves

Regression Statistics	
Multiple R	0.96518
R Square	0.931572
Adjusted R^2	0.929365
Standard Error	0.270242
Observations	33

ANOVA

	df	SS	MS	F	Signif. F
Regression	1	30.82132	30.82132	422.03366	1.29799E-19
Residual	31	2.263945	0.07303		
Total	32	33.08526			

	Coeff.	Std. Error	t Stat	P-value	Lower 95%	Upper 95%
Intercept	-0.23158	0.065278	-3.54752	0.0012613	-0.364711528	-0.098439906
Slope	-0.08298	0.004039	-20.5435	1.298E-19	-0.091216458	-0.074740575

Half Life =   8.353333   Days

Predicted DFR Levels

Time (Days)	Residue (ug/cm2)	Time (Days)	Residue (ug/cm2)
0	0.793283	21	0.1388828
1	0.730114	22	0.1278237
2	0.671976	23	0.1176452
3	0.618467	24	0.1082773
4	0.569219	25	0.0996552
5	0.523893	26	0.0917198
6	0.482176	27	0.0844162
7	0.44378	28	0.0776942
8	0.408443	29	0.0715075
9	0.375919	30	0.0658134
10	0.345985	31	0.0605728
11	0.318434	32	0.0557494
12	0.293078	33	0.0513101
13	0.26974	34	0.0472244
14	0.248261	35	0.0434639
15	0.228492		
16	0.210298		
17	0.193552		

18	0.178139
19	0.163954
20	0.150899

Regression Analysis: Means and CVs for California Pepper Leaves

Days after Last Treatment	Residues (ug/cm2)	Mean (ug/cm2)	Standard Deviation (ug/cm2)	Coefficient of Variation (%)
0	0.669	0.716	0.0487	6.8
	0.766			
	0.712			
0.25	0.561	0.615	0.0674	11
	0.593			
	0.691			
1	0.658	0.698	0.0347	4.97
	0.712			
	0.723			
2	0.626	0.658	0.0656	9.97
	0.615			
	0.734			
4	0.572	0.629	0.0498	7.92
	0.658			
	0.658			
7	0.486	0.507	0.0216	4.26
	0.529			
	0.507			
10	0.265	0.354	0.0783	22.1
	0.410			
	0.388			
14	0.265	0.329	0.058	17.6
	0.345			
	0.378			
21	0.110	0.195	0.0751	38.5
	0.254			
	0.221			
29	0.040	0.0504	0.0148	29.4
	0.067			
	0.044			
35	0.031	0.0456	0.0176	38.6
	0.065			
	0.041			

**Regression Analysis: Log of Dislodgeable Foliar Residue
vs. Time for California Pepper Leaves**